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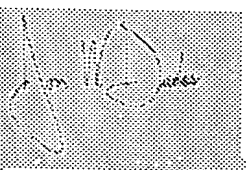
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APPLICATION NUMBER: 60/523,589  
FILING DATE: *November 19, 2003*  
RELATED PCT APPLICATION NUMBER: *PCT/US04/39077*

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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**  
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

**INVENTOR(S)**

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Dr. Jon	Mandelbaum	Indianapolis, Indiana

☐ Additional inventors are being named on the \_\_\_\_\_ separately numbered sheets attached hereto

**TITLE OF THE INVENTION (280 characters max)**

SURGERY TOOL COVER AND TROCAR CLOSURE PATCH

Direct all correspondence to:

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**ENCLOSED APPLICATION PARTS (check all that apply)**

☒ Specification, Claims and Abstract Number of Page 7  
☒ Drawing(s) Number of Sheets 2  
☒ Small Entity Statement  
☐ Other (specify) \_\_\_\_\_

**METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)**

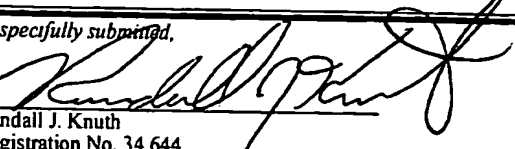
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Respectfully submitted,

Date: November 19, 2003

  
Randall J. Knuth  
Registration No. 34,644

Docket No.: MAB-5

Telephone No.: 260-485-6001

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED

"EXPRESS MAIL" COVER LETTER

Date: November 19, 2003

Commissioner of Patents and Trademarks  
Box: Provisional Application  
Alexandria, VA 22313-1450

Re: Provisional Application for United States Letters Patent

APPLICANT: Dr. Jon Mandelbaum

TITLE OF INVENTION: SURGERY TOOL COVER AND TROCAR CLOSURE PATCH

ir:

Forwarded herewith is the above-identified application, consisting of the following:

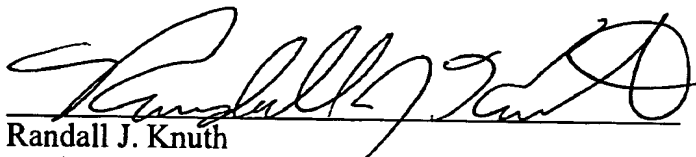
PTO/SB/16

Specification, Claims and Abstract (7 Sheets)

Drawings (2 Sheets)

Applicant claims small entity status. See 37 CFR 1.27.

Respectfully submitted,



Randall J. Knuth

Registration No. 34,644

JK/mdc

Enclosures: As stated above.

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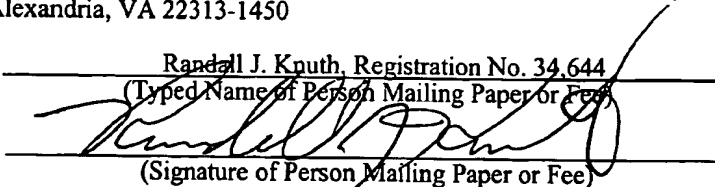
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# SPECIFICATION

[Electronic Version 1.2.8]

## [SURGERY TOOL COVER AND TROCAR CLOSURE PATCH]

### Summary of Invention

[0001] | The present invention, in one form thereof, includes a surgery tool cover for facilitating protected introduction of a surgical element (e.g., a circular stapler, specimen removal device) into the body, especially a surgical element requiring expansion of its occupied volume after insertion into the body. Such a surgical tool cover includes a hinged, mating pair of tool cover sections that are normally biased together so as to define a closed volume in which a tool can be carried and includes a handle via which the surgery tool cover and a tool carried therewithin can be held. The handle is further configured for opening the cover sections via the hinge so that the tool carried within the cover can be used.

[0002] The present invention, in another form thereof, is a trocar closure patch configured for being mounted from the inside of a trocar opening, previously formed in the body for a surgical procedure, to thereby effectively close such an opening. The material of such a patch is chosen so as to be biologically compatible so as to not require a later procedure to remove it from the body.

[0003] One advantage of the tool cover of the present invention is that it protects the tool being carried therewithin from the interior of the body and/or from body fluids, thereby keeping it cleaner.

[0004] Another advantage of the tool cover of the present invention is that it also helps to avoid undesired contact with interior body portions by the tooling. As such, the tool cover can potentially avoid or at least minimize the introduction or transference of viruses, microbes, bacteria, and/or infected/cancer cells within the body. Further, the tool cover also reduces the opportunity for physical damage (i.e., scrapes, tears, and/or cuts) that may otherwise occur by contact with the tool carried within the cover. Such physical damage that could be introduced by the tool cover itself is minimized by the provision rounded edges and/or round shapes for the tool cover.

- [0005] Yet another advantage of the tool cover of the present invention is that it is ideally made of a flexible/elastomeric polymeric material (e.g., rubber, polyurethane) that is biologically inert and not readily susceptible to permitting viruses, bacteria, microbes, and/or infected/cancer cells to be transmitted therethrough or thereby.
- [0006] A further advantage of the tool cover of the present invention is that it is configured so as to form a closed cone, cylinder, or other shape (i.e., thereby creating a volume in which a tool can be carried) except when the handle of the tool cover device is squeezed/activated to hingedly open the cover section. By having a tool cover be in a normally closed position, there is increased protection of both the tool carried within the cover (from possible bodily and originating contaminants) and the surrounding body portions (from unwanted tool contact).
- [0007] The hinge action may be achieved through the provision of one or more separate hinge elements or may be integral to the tool cover. In an integral hinge situation, both cover sections are integrally connected to a same joining portion. The ability to behave as a hinge is afforded due to the flexibility of the material used in forming the surgery tool cover. The use of such an integral hinge is advantageous in that there is no additional hardware associated with the surgery tool cover which could potentially have undesirable contact with interior body tissue.
- [0008] An additional advantage of the tool cover of the present invention is that the end proximate the handle can be provided with a rubber/elastomeric diaphragm to thereby adjoin the cover sections. Such a diaphragm can further include an inlet to thereby allow multiple-size staple guns or other surgical tools to be inserted thereinto and/or retrieved therefrom.
- [0009] An advantage of the trocar closure patch of the present invention is that it is actually able to use the interior body pressure to create a tighter seal with the skin, muscle, or other tissue being closed to thereby more effectively close a given opening (this is a contradistinction to a closure patch on the outside of the body, in which the interior body pressure actually places a tensile stress on the sutures used to hold the closure patch in place).
- [0010] Another advantage of the trocar closure patch of the present invention is that the patch material can be chosen so as to be biologically compatible. This patch material could be dissolvable over time or capable of being incorporated into the body. Such incorporation could be either by acting as a matrix for new tissue growth into the location occupied by the patch or by actually growing to match the surroundings (i.e., as per developing pig liver tissue technology).

[0011] Yet another advantage of the present invention is that the patch material can gain its biological compatibility by being essentially biologically inert (e.g., surgical gold) and thus acceptable to remain permanently within the body.

[0012] A further of the trocar closure patch of the present invention is that such patches can come in a variety of sizes and/or shapes to accommodate any of a variety of surgical/trocar openings within the body and/or body parts, including both circular trocar openings and linear incisions.

[0013] An additional advantage of the trocar closure patch of the present invention is that it has anchoring sutures associate directly therewith to thereby facilitate the mounting of the patch in a desired location. Further, such suture may be color-coded for ease of use.

[0014] Yet another advantage of the trocar closure patch of the present invention is that it can have a related suture passer for use therewith. Advantageously, such a suture passer is disposable, making it more sanitary and convenient to use.

## Brief Description of Drawings

[0015] The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of the embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

[0016] Fig. 1 is a side, perspective view of a surgical tool holder of the present invention in its closed position;

[0017] Fig. 2 is a side, perspective view of a surgical tool holder shown in Fig. 1, in its open position; and

[0018] Fig. 3 is a perspective view of a trocar closure patch of the present invention.

[0019] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplification set out herein illustrates at least one preferred embodiment of the invention, in one form, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

## Detailed Description

[0020] Surgical tool cover 10 (Figs. 1 and 2) include a tool enclosure 12 and a handle 14. The tool enclosure 12 includes a first tool cover section 16, a second tool

cover section 18, and a cover diaphragm (cover base) 20. Further associated with tool enclosure 12 is a diaphragm inlet 22 and a cover hinge 24.

[0021] Tool enclosure 12 (especially sections 16 and 18) are advantageously made of a flexible/elastomeric polymer (e.g., rubber, polyurethane) that is biologically inert or at least durable to exposure to surgical environments. Ideally, such a material is not susceptible to permitting viruses, bacteria, microbes, and/or infected cells to be readily transmitted therethrough or thereby. By being made of such a material, tool enclosure 12 advantageously would be able to protect the tool carried therewithin (e.g., a circular stapler, a specimen removal device, or other surgical items) from the body interior including any gastrointestinal contents of other body fluids, as well as protecting the interior of the body from contact with the tool (not shown) carried within enclosure 12. By protecting the tool from the interior of the body and/or body fluids, tool cover 10 effectively helps keep the tool cleaner and less susceptible of transfer of any diseases within a patient being operated on or to other patients in which the tool may later be used.

[0022] Tool enclosure 12 is provided with first and second tool cover sections 16, 18 as well as a cover hinge 24 so as to permit a tool to be carried within enclosure 12 in an essentially enclosed environment except when the tool is to be used. Specifically, first tool cover section 16 and second tool cover section 18 are mounted so as to normally be biased into mating contact with each other to thereby, along with cover diaphragm 20, form an essentially enclosed volume. Such an enclosed volume advantageously takes the form of a cone, cylinder, or other rounded shape. A conical shape is useful for such a tool as it aids in insertion into a body portion. Tool enclosure 12 is shown in its closed form in Fig. 1.

[0023] As seen in Fig. 2, the provision of cover hinge 24 permits first tool cover section 16 to be dilated from second tool cover section 18 to permit use of the inserted tool (not shown) such as a stapler in a desired location. Advantageously, handle 14 is designed so that squeezing thereof will appropriately activate hinge mechanism 24 to drive section 16 and 18 into their dilated position, in a manner similar to a speculum.

[0024] Cover hinge 24 is advantageously an integral hinge produced by the flexible interaction of the adjoinment of first and second sections 16 and 18 with cover diaphragm 20. By having cover hinge 24 be an integral hinge, there are no additional parts which could potentially become contaminated and require cleaning and/or which could potentially produce some degree of physical trauma if it should come into contact with an interior body portion. On the other hand, there may be instances in which a separate hinge mechanism 24 may at least prove useful in order to gain a more controllable hinge operation (e.g., open only a limited amount and/or in a more controllable manner). Additionally, a separate hinge may reduce the opportunity for

tearing of any one of the cover sections 16 and 18 and/or cover diaphragm 20 by providing further support at the point of bending.

[0025] Diaphragm inlet 22 provides a location through which the surgical tool can be introduced or removed during a surgical procedure. By having such a hole provided in cover diaphragm 20, it is possible to use the same surgical tool cover 10 as a cover for multiple surgical tools during a given operation.

[0026] Advantageously, tool enclosure 12 can be further provided with a rubber lining (not shown) to further protect the interior thereof from exposure to gastrointestinal contents.

[0027] Trocar closure apparatus 30 is configured for mounting and closing a trocar opening from the interior of the body and/or organ/tissue to thereby effectively close that given opening (not shown). Trocar closure apparatus 30 includes a trocar closure patch 32 and a plurality of anchoring sutures 34. Trocar closure patch 32 can be further provided with suture holes 36 which aid in the mounting of the anchoring sutures relative to patch 32.

[0028] A key feature of closure patch 32 is that it is biologically compatible with the surrounding tissue at a trocar opening. Such a patch material can be dissolvable or capable of being incorporated into the body. Such incorporation may take the form of acting as a matrix for new tissue growth or actually growing to match the surrounding (i.e., pig liver tissue technology). Alternatively, the patch material could be biologically inert (e.g., surgical gold) and acceptable to remain permanently in the body.

[0029] There are other features which the patch material should possess in addition to being biologically compatible. Surgical material should help produce a fluid-type seal and essentially fully retard bleeding at the opening that it is being used to close. Additionally, the patch material should be flexible enough to allow for body movement so as not to be loosened easily.

[0030] Trocar closure patch 32 can advantageously be produced in multiple sizes and shapes to thereby accommodate different sizes of trocars/incisions. It is to be understood that, by being producible in forms of various sizes and shapes, such a closure apparatus 30 could be used in helping to close a standard straight incision as well as a generally circular trocar opening.

[0031] Anchoring sutures 34 may be color coded for ease of their application. Additionally, a disposable suture passer could come with each trocar closure apparatus 30. The disposable nature of such a suture passer (not shown) is that it is both sanitary and convenient.



[0032] While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

## Claims

[c1]

1. A surgery tool cover configured for facilitating an introduction of a surgical element in a protected manner within a portion of a body, said surgery tool comprising:

a hinged, mating pair of tool cover sections, said tool cover sections mating in such a manner so as to be normally biased together to define a tool-receiving volume capable of receiving a surgical tool therewithin; and

a handle operatively connected to at least one of said tool cover sections, said handle being selectively operable to hingedly move said tool cover sections away from one another and thereby create an opening therebetween, said opening therebetween being sufficient to permit utilization of the surgical tool received with said tool-receiving volume.

[c2]

2. A trocar closure patch configured for mounting from an interior side of a surgical body opening, said trocar patch comprising:

a patch of biologically compatible material, said patch being sized so as to completely cover said surgical body opening, said patch being composed of a material which can remain in a body without need for a procedure for later removal thereof.

## Abstract of Disclosure

[0033] A surgery tool cover facilitates protected introduction of a surgical element (e.g., a circular stapler, specimen removal device) into the body, especially a surgical element requiring expansion of its occupied volume after insertion into the body. Such a surgical tool cover includes a hinged, mating pair of tool cover sections that are normally biased together so as to define a closed volume in which a tool can be carried

and includes a handle via which the surgery tool cover and a tool carried therewithin can be held. The handle is further configured for opening the cover sections via the hinge so that the tool carried within the cover can be used.

## Figures

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PAGE 14/15

P. 2

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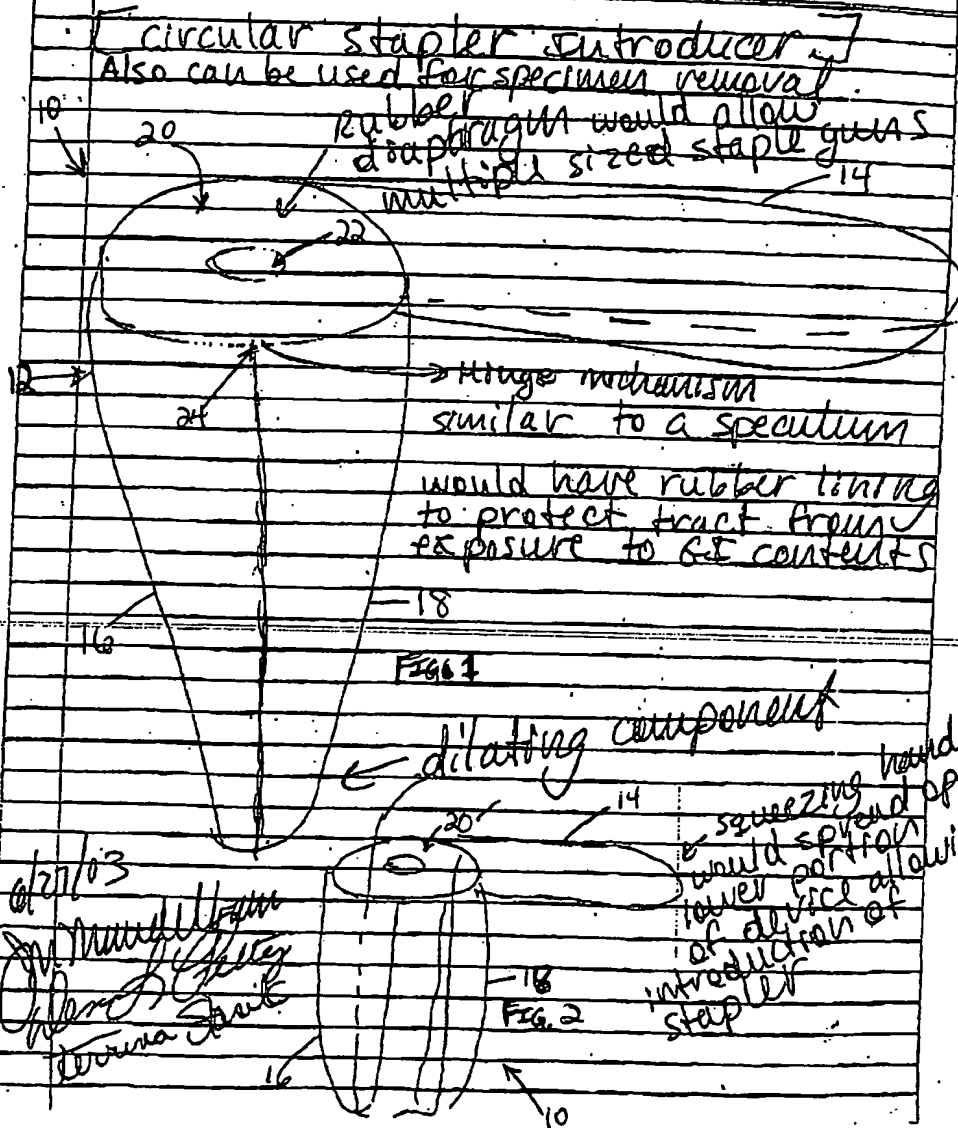
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PAGE 15/15

P. 3

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TROCAR Closure Patch

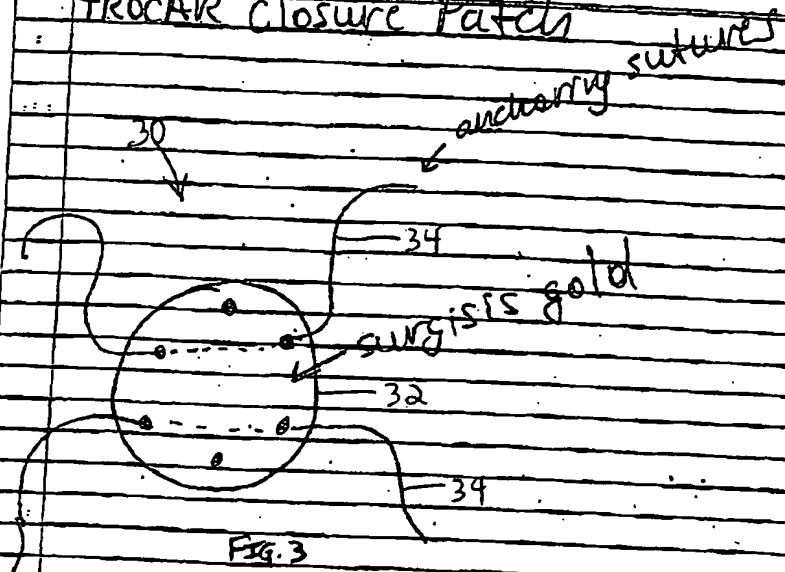


Fig. 3

would have the sutures color coded for ease of application. A disposable suture passer could come with patch, would offer @ least 2 different sizes of patches for different sizes of trocars.

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# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US04/039077

International filing date: 19 November 2004 (19.11.2004)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/523,589  
Filing date: 19 November 2003 (19.11.2003)

Date of receipt at the International Bureau: 23 December 2004 (23.12.2004)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



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